

performed as a whole. Moreover, the State's fate and transport analysis more than meets the requirements of Fed. R. Evid. 702 and the *Daubert* standard. *See, e.g., Fisher v. Ciba Specialty Chemicals Corp.*, 2007 WL 2302470, *6 (S.D. Ala. Aug. 8, 2007) (holding that "it is simply not true that quantitative scientific evidence is the only way to establish causation in an environmental contamination case, or that the inferential methodology . . . is inherently unreliable because it is circumstantial").

Drs. Fisher, Engel and Olsen provided detailed evidence, by affidavit and testimony, about the fate and transport work done in this case. *See* Off. T., 312:14-352:21 (Ex. B), 421:21-447:17 (Ex. B), and 784:5-798:9 (Ex. C). First, the testimony reveals that there is a source of poultry waste in the IRW; that the amount of waste was calculated; and that a significant portion of the waste generated is land applied in the IRW. *See* Off. T., 315:1-320:10, 333:1-11, and 421:21-447:17 (Ex. B). Dr. Fisher studied the geology of the IRW to determine how poultry waste is transported in the environment. *See* Off. T., 333:12-344:5 (Ex. B) and 352:4-21 (Ex. B). In addition, Camp Dresser & McKee conducted extensive sampling in the IRW. *See* Off. T., 784:5-798:9 (Ex. C). Relying on that sampling, existing and ongoing sampling by the USGS and other entities as well as scientific literature, the State's experts, including Drs. Fisher and Olsen, studied the constituents of poultry waste and followed the movement of those constituents each step along the pathway—beginning with the waste itself, then the fields, the edge of fields, the surface water, sediments, springs, ground water of the IRW, and finally Lake Tenkiller. *See generally* Off. T., 312:14-352:21 (Ex. B) and 784:5-798:9 (Ex. C). Dr. Fisher also performed a paleolimnological investigation of Lake Tenkiller and determined that the increased levels of phosphorus correlated with the increased levels of other constituents commonly found in poultry waste, which further buttresses his opinion regarding the source of contamination in the IRW.

See Off. T., 347:3-350:6 (Ex. B). As set forth in their testimony and affidavits, Drs. Teaf, Harwood, and Lawrence relied, in part, upon this fate and transport analysis to render their opinions regarding the human health risks resulting from land application of poultry waste.

In addition, the State performed additional analyses, namely PCA and Microbial Source Tracking (“MST”) through PCR, which are the subject of Defendants’ motions. While Defendants claim that PCA and PCR are the lynchpins of the State’s case, the State submits that these analyses are merely additional lines of evidence in the weight of evidence approach taken by the State’s experts. *See, e.g.*, Olsen Test. (Off. T., 777:13-778:13 (Ex. C)); Teaf Test. (Off. T., 207:3-211:9 (Ex. A)); and Harwood Test. (Off. T., 672:17-673:9 and 709:4-8 (Ex. C)); *see also* State’s Exhibit 403 (Ex. J). Neither analysis operates as the sole evidentiary basis for the State’s Motion for Preliminary Injunction. Rather, they each provide further substantiation of the State’s fate and transport evidence.

B. PCA Employed by Dr. Olsen Is A Reliable Scientific Method

Defendants attack Dr. Olsen’s selection of samples and individual components for the PCA as “questionable,” but provide no substantive foundation for their attacks. Their primary criticism appears to be the number of samples in the analysis. Dr. Olsen clearly explained that not all 2,661 samples were analyzed for all 25 parameters of the PCA and that he used a stratified random sampling design to assure that the 621 samples selected for full analysis provided a representative sampling of the watershed. *See* Off T., 875:4-876:6 and 877:3-16 (Ex. D). Therefore, Defendants’ attempt to represent to this Court that the 25 parameters were “undetectable” in over 75 percent of the environmental samples is, at best, misleading. In addition, a plain reading of Defendants’ brief shows that they have made no real substantive issue of the 25 components and why their selection was improper. They merely speculate that

the peer review process might reveal some unspecified error. *See* Def's Brief, at 7-8. Such speculation is no basis for excluding, limiting, or affording less weight to Dr. Olsen's testimony.

Defendants' motion relies heavily on the affidavit of Dr. William Huber, stating that it sets forth the most "devastating critique of Dr. Olsen's methodology." Defs.' Brief, at 9. The evidence relied upon by the Defendants to criticize the work of Dr. Olsen is simply the general allegations of Dr. Huber set forth in his affidavit. Dr. Huber never testified before the Court nor was he subject to cross examination. The only specific testimony before the Court concerning Dr. Huber's general allegations in his declaration is the contrary testimony of Dr. Olsen. It is generalized, makes erroneous factual assumptions and his testimony was never subject to cross-examination. Further, he criticizes Dr. Olsen's PCA without stating to any degree of specificity the impact (if any) that his criticisms had on Dr. Olsen's ultimate conclusions. Importantly, Dr. Huber ran the PCA and could have testified regarding the same. *See* Daily T., 1741:15-18; 1783:18-22. However, Defendants did not call Dr. Huber at the hearing, so all that stands are his unsubstantiated uncross-examined criticisms. Giving substantial weight to Dr. Huber's affidavit in this context is improper. *See, e.g.,* 11A Fed. Prac. & Proc. Civ. 2d §2949 ("When the outcome of a Rule 65(a) application depends on resolving a factual conflict by assessing the credibility of opposing witnesses, it seems desirable to require that the determination be made on the basis of their demeanor during direct and cross-examination, rather than on the respective plausibility of their affidavits."). If Dr. Huber ran the analysis and any of these critiques had a substantial impact on the results, one wonders why Defendants did not proffer his testimony.

Defendants argue that Dr. Olsen did not take into consideration other major contributors of bacteria and that he should have run a PCA to determine a signature for cattle. Defendants' Brief, at 8. However, Dr. Olsen did, in fact, examine the published scientific literature to

determine how the poultry signature compares to the concentrations of the 25 parameters contained in cattle manure. As he testified:

Well, you can see that this is the way principal component works. If the waste is there and it's significant, for instance, the cattle waste or the wastewater treatment plant, but the sampling we did, you're going to see that waste signature if it's significant. We, of course, saw the wastewater treatment plant signature. We didn't see the cattle signature. My conclusion is the cattle signature is not significant. I went to specific samples that I knew had cattle waste in it, and I could see a distinct difference particularly with the poultry waste. So I knew what I was looking for, and it just wasn't a dominant signature across the basin. I found it in like significantly in one spring sample, and I found it not significant in three other spring samples. I found it significant in four edge of field samples and not so significant in five others. It's not a dominant signature across the basin. If it would have been, I would have found it.

Off. T., 844:14-845:5 (Ex. C). Thus, Dr. Olsen did take reported values of cow manure into account when trying to identify whether the signature was derived from poultry waste. He also conducted an analysis of whether a cattle signature was dominant across the watershed. It was not. It is noteworthy that Defendants criticize the use of PCA for multiple source contamination and yet advocate the use of a cattle signature. In any event, contrary to Defendants' assertions, Dr. Olsen did take other sources of contamination into account, including an evaluation of waste water treatment effluent and literature values on cattle.

Moreover, Defendants' attempt to parse out component by component Dr. Olsen's analysis completely misses the mark. PCA is a complex statistical analysis that analyzes the relationships of various selected parameters. Taking each component alone renders the purpose of the analysis meaningless. It is the relationship of the various components to one another that determines the results of the analysis. Defendants' criticisms are, therefore, baseless.

Likewise, Defendants' contention that Dr. Olsen did not examine whether the parameters of the poultry waste signature correlate in the environment is simply untrue. Defs.' Brief, at 8. Dr. Olsen selected several control or reference streams to determine whether the poultry

signature occurred in an unimpacted environment and found no evidence of the poultry signature. *See* Off. T., 898:8-899:12 (Ex. D). Moreover, Dr. Hennes acknowledged that Dr. Olsen conducted this analysis. *See* Daily T., 1771:4-11 (Ex. F).

Dr. Olsen's work in this case is reliable. Defendants repeat their argument that Dr. Olsen's PCA has not been peer-reviewed or published. However, despite Defendants' contention that peer review and publication are required, the *Daubert* Court noted otherwise:

Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published. Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593-594 (1993) (citations omitted). While it may be true that Dr. Olsen's use of PCA in this case has not been the subject of peer review, he has published an article on his use of PCA in determining the source of arsenic contamination in an EPA superfund site. *See* Off. T., 780:8-21 (Ex. C). Moreover, as the *Daubert* Court held, peer review is but one factor to consider. As noted above, Dr. Huber has reviewed Dr. Olsen's work in this case and has run the analysis. Therefore, it is capable of being tested.

Likewise, Dr. Olsen's methodology is generally accepted in the scientific community. Moreover, despite Defendants' arguments with respect to PCA's utility in the context of multiple potential sources of contamination, Dr. Hennes agreed that "[s]ometimes [PCA] is perfectly fine" to do an environmental investigation of sources. *See* Daily T., 1737:11-16 (Ex. F). Indeed, Dr. Hennes himself used PCA to identify source of contamination in an environmental case as early

as 1981. *See generally* Daily T., 1738-1739 (Ex. F). Any argument that PCA is not a reliable methodology to assist in identifying the source of contamination in an environmental case fails.

Finally, Defendants argue, “The conclusion is untested, uncorroborated, unreviewed, and ultimately, unsupported.” Again, despite Defendants’ protestations to the contrary, the heart of the matter lies with the weight to be afforded Dr. Olsen’s conclusions, not the reliability of his methodology. Defendants attempt to poke holes in the methodology without showing that, even if valid, their criticisms would have any effect on the conclusions reached by Dr. Olsen. They had the opportunity and apparently the time to conduct the analysis (as demonstrated by Dr. Hennessey who testified that Huber ran the analysis) and proffer substantive evidence related to Dr. Olsen’s ultimate conclusions, but did not do so.

C. Dr. Harwood’s MST Methods are Reliable

As previously submitted, Dr. Harwood’s microbial source tracking work utilizing the PCR methodology is accepted and reliable. Defendants’ criticisms of her work miss the mark and, in many instances, are just flat wrong. First, while Dr. Harwood did not prepare the sampling plan for the overall sampling, she had more than a guiding hand in the work performed by North Wind laboratory. *See* Off. T., 631:11-19 (Ex. C). Harwood worked in conjunction with North Wind to develop a PCR assay for bacteria that are associated with poultry waste. Any assertion to the contrary is simply untrue.

Defendants argue that Dr. Harwood failed to use statistically significant sample numbers. Peer-reviewed, published articles employing MST, however, have used fewer samples than Dr. Harwood. *See* State’s Exhibits 532 and 536 (Exs. K and L). Defendants continue to criticize Dr. Harwood for performing work comparable to peer-reviewed published work conducted by other

well-respected MST experts, including Defendants' own expert Mansour Samadpour. These criticisms are baseless.

Defendants argue that Dr. Harwood's methodology is in doubt because she did not test every animal in the watershed. That is simply absurd. Dr. Harwood tested animals with the greatest potential for contributions to watershed: humans, cattle, swine, ducks, and geese. Further analysis would have been unfruitful based on the amount of feces contributed to the watershed by other species. Dr. Harwood cannot be faulted for failure to test muskrat and terrapin feces. Such a criticism is ludicrous.

Defendants criticize Dr. Harwood's work arguing that there is no correlation between the poultry biomarker and fecal indicator bacteria found in the watershed. This assertion is just plain wrong. First, Dr. Harwood testified regarding the correlations of the poultry biomarker to enterococcus as well as the correlations of other indicator bacteria. *See* Off. T., 669:20-672:7 (Ex. C); State's Exhibits 439, 438, and 440 (Ex. M). Second, Dr. Myoda admitted during cross-examination that he used the wrong numbers for his correlation between poultry waste and the poultry biomarker and that there does appear to be a correlation between the poultry biomarker and enterococcus when the right numbers are analyzed. *See* Daily T., 2089:7-2094:25 (Ex. G). Moreover, as noted by Dr. Teaf and Dr. Sullivan, exceedances of enterococcus are predominant in the watershed. Therefore, Defendants' attempt to invalidate Dr. Harwood's methodology on the basis of lack of correlation fails.

Dr. Harwood has been completely forthcoming with respect to the new aspects of her work. As she testified, the "novel" part of her analysis deals only with the fact that she was asked to work with poultry fecal matter in this case. The methods she employed, however, are not novel. For example, as Dr. Myoda acknowledged, PCR is generally accepted and widely

used. *See, e.g.*, Daily T., 2034:8-13 (Ex. G). It is the application of her methods to poultry waste that Defendants criticize. However, Defendants fail to acknowledge that the EPA has conducted similar analyses with respect to poultry fecal DNA with outcomes that are consistent with Dr. Harwood's findings. *See* State's Exhibit 536 (Ex. L). Therefore, Dr. Harwood's methodology is not as "unique" as Defendants would have this Court believe. *See also* Sullivan Test. regarding work conducted in Tillamook Bay, Daily T., 2266:13-2267:13 (Ex. H).

It is true that Dr. Harwood's opinions reached in this case are, to date, unpublished and not the subject of peer review. As she testified, however, there is a manuscript in draft. Moreover, an abstract has been submitted and will be presented in June of this year. *See* Off. T., at 661:10-15 (Ex. C). And, like Dr. Olsen, Dr. Harwood has published on MST and the methodologies that she employed in this case, just not as applied to the poultry waste biomarker. *See* Off. T., at 630:13-18 (Ex. C); State's Exhibit 59-1 (Ex. N). As noted above, peer review and publication are but one of the things to consider under *Daubert*. Dr. Harwood's work can be tested and reproduced. Defendants have merely chosen not to conduct those tests—presumably because of their fear of further validating her analysis. In fact, other than bald criticisms intended to cast doubt on Dr. Harwood's MST work in this case, Defendants have proffered no evidence at all that it is unreliable.

Defendants argue that the State is asking the Court to take a leap of faith and forego full fate and transport analysis. However, as noted above, an independent fate and transport analysis was conducted by the State's experts. This analysis stands no matter what weight this Court accords Dr. Harwood's work. Moreover, one cannot ignore that Dr. Harwood also traced the pathway of the poultry biomarker. She looked at poultry waste, field samples where waste was land applied, the edge of field samples, groundwater samples, and surface water samples.

Moreover, Dr. Harwood found the poultry biomarker in all of those locations. *See* Daily T., 2082:6-16 (Ex. G). Such analysis demonstrates the pathway of the poultry biomarker and, when viewed with Dr. Harwood's correlations, the pathway of bacteria derived from poultry waste.

Finally, even if Defendants were correct that MST is not at a point that it can provide the sole basis for a finding with respect to source of contamination, it still constitutes one of the lines of evidence regularly employed by the EPA and other regulatory agencies to make such a determination. For example, as set forth in her testimony, Dr. Harwood is performing a similar analysis in the Gulf of Mexico in a research grant funded by the EPA. State and federal agencies use MST, as the State is using it in this case, in conjunction with other lines of evidence. The State does not ask this Court to grant its motion solely on Dr. Harwood's findings, only that it give her analysis and conclusions substantial evidentiary weight along with the State's other lines of evidence.

II. Conclusion

As noted by both Defendants and the Court, these motions are really ones regarding the weight this Court will give Dr. Harwood's PCR testimony and Dr. Olsen's PCA testimony. As noted above, the State has presented a number of lines of evidence supporting its claim that the land application of poultry waste in the IRW creates an imminent and substantial endangerment to human health. Based on the foregoing, the State respectfully requests that the Court deny Defendants' motions and give considerable weight to Dr. Harwood's and Dr. Olsen's testimony.

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